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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,910	03/09/2004	Kenneth J. Michlitsch	USGINZ00600	3380
40518 7590 09/10/2009 LEVINE BAGADE HAN LLP 2400 GENG ROAD, SUITE 120 PALO ALTO, CA 94303				
EXAMINER				
PEFFLEY, MICHAEL F				
ART UNIT		PAPER NUMBER		
3739				
MAIL DATE		DELIVERY MODE		
09/10/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/797,910

**Applicant(s)**

MICHLITSCH ET AL.

**Examiner**

Michael Peffley

**Art Unit**

3739

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8, 11, 12 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8, 11, 12 and 32-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date \_\_\_\_\_
- 6) ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 22, 2009 has been entered.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 11, 12 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (6,258,087) in view of the teaching of Saadat et al (2003/0233026).

As best shown in Figures 70 and 71, Edwards et al provide an endoluminal GI device that includes an elongate shaft (284) for placement in the GI lumen, a plurality of suction ports (306) substantially aligned along the shaft and connected to a source of suction, and electrodes (312) disposed on the shaft in proximity to the suction ports for introduction into tissue and delivery of RF energy. The examiner maintains the electrodes are inherently capable of "leaving an identifiable mark" on an outer surface of the GI lumen. As see in Figure 71, the surface tissue is held immediately adjacent the

electrode tip and the vacuum port. While Edwards et al may disclose in other embodiments that the intention is to create deeper lesions below the mucosal surface, the device remains inherently capable of leaving marks at the surface by controlling the depth of penetration of the needles and/or the amount of energy delivered through the electrodes. That Edwards et al may prefer a deeper lesion below the surface does not preclude the Edwards et al device from being used to create surface lesions, particularly in the embodiment of Figures 70 and 71 where the needle remains so close to the tissue surface given the angle of penetration. Edwards et al also disclose an inflation element (288,290). As addressed in the previous Office action, Edwards et al inherently provides for a suction pump at the proximal end, and also includes a handle assembly with pull wires. Edwards et al, however, fail to disclose the endoscope device being flexible in a first state and substantially rigid in a second state.

Saadat et al disclose another endoscopic device and specifically teach of an endoscope that is flexible for navigating a tortuous pathway. Once in position, Saadat et al teach the endoscope may be "rigidized" (see abstract) to maintain the desired curvature in the body lumen.

To have provided the Edwards et al endoscopic device with a means to make the device rigid once a desired body location is reached to enable the device to conform to the body area would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Saadat et al.

***Response to Arguments***

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

The examiner maintains the Saadat et al reference fairly discloses that it is known to provide endoscopic devices with rigid and flexible states, and that one of ordinary skill in the art would be fairly motivated to provide such states to the Edwards et al endoscope so the device may better conform to body curvatures during use.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/  
Primary Examiner, Art Unit 3739

/mp/  
September 8, 2009